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EC AIM Project 1026

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DATA SETS ABOUT PATIENTS

LEGAL AND ETHICAL ISSUES

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Data processing is blossoming within medical practice. Programmes are being created, research projects are being set up, notably within the framework of European institutions. Project CHIC (Community Health Information Classification and Coding), part of the European programme AIM (Advanced Informatics in Medicine), is designed to serve the goal of providing a basic level of compatibility in information systems for ambulatory care.

It has proposed two collective-types of data (1) :

- the minimum basic data set (MBDS) designed to communicate to a doctor quickly, effectively and in a standardized form, the basic information relative to a contact with another physician ;

- the patient related data set (PRDS) intended to integrate in a single record the minimum of data concerning a patient necessary to appreciate the all-round state of health of the patient or indispensible in the event of a doctor transferring the care of one of his patients to a colleague. It includes the personal details of the patient, an overview of his general health characteristics and a review of his medical history and current problems.

Faced with these proposals, it is valuable to verify to what degree the legislations of various nations, in particular Belgium, permit, encourage, or limit the right to collect or transmit such information whether personally or anonymously. Such is the object of this study.

1. OBLIGATIONS TO ACTION

1.1. The obligation to keep a medical record

The keeping of a medical record is not a legal obligation, but the code of medical ethics enjoins a doctor, as a matter of principle, to keep a file on each patient (2).

A "licensed" general practitioner must keep up to date records of all his patients (3).

Hospitals are equally obliged to keep up to date records of all patients (4).

When a patient leaves hospital, his medical file must be classified and retained in the archives, preferably centrally. Such files must be permanently accessible to any doctor treating the patient.

Nowhere is precisely stated just what such a medical file should contain, except that the hospital file must include "all the elements necessary to ensure diagnosis, adequate treatment and the ability to follow the development of the illness" (5). According to the opinion of the Council of the Order of Physicians, the record constitutes neither an "inventory" of a doctor's activities nor a "full accounting" of his services. Such purely negative parameters evidently leave a lot of latitude to the practitioner, thus guaranteeing his liberty, but are of little use in helping to create an instrument of quality, giving satisfactory service in relation to the needs defined.

In order to assist young doctors in their first steps in this respect, the Centre for General Practice at the University of Louvain has conceived a model medical record (handwritten at this point) which has been reviewed in a report on medical files (6).

1.2. Rights and obligations relative to the transmission of information

In certain cases, the depositor of medical information may or must transmit it, in spite of the general principle of professional secrecy (which will be treated in section 2). In this respect, one must distinguish between the obligation to communicate information to the patient (see 1.2.1.), cases where the transmission of data is tolerated or required by law, or in the event of particular imperatives such as : the quality of treatment, the protection of the rights of patients, the right of society, public health or requirements of epidemiological knowledge.

1.2.1. Transmission of information to the patient

The code of medical ethics requires the revealing of a prognosis to the patient (7). However, there is an exception made for prognoses of a grave (the doctor must decide) of fatal nature (the doctor is enjoined to prudence).

1.2.2. Cases where the transmission of information to third parties is permitted

a) Testifying

A doctor called to testify in a court of law may speak, however, the law does not oblige him to. On the contrary, his ethical code forbids it.

Similarly, those who have access to social data of a personal nature by way of their employment in the Social Security system, may testify in a court of law or in other proceedings regulated by law (8).

b) Epidemiological surveillance

A superior Board has been charged with the coordination of the fight against AIDS (9). It is attached to the Institute of Hygiene and Epidemiology and monitors the epidemic in collaboration with medical record pilot-centres and sentinel doctors.

1.2.3. Cases where the transmission of personal information is obligatory

A doctor is required to communicate certain types of personal data in a series of cases imposed by law or in pursuance of a law :

a) Quality of treatment, notably the continuity of treatment
. communications between doctors in the interest of treating the patient
. the relationship between preventive and curative personnel
b) Protection of the rights of the patient
. contacts with the health insurance system
. contacts with a medical inspector empowered to examine the patient's case with regard to his or her rights
c) Rights of society
. registration of births
. registration of deaths
. certificate of collocation
. accounting of financial outlays and control of eventual abuses
d) Public health
. declaration of epidemics
. sanitary inspection of convalescent homes
e) Epidemiological research
. gathering of health statistics
. statistical information about hospitals
. congenital anomalies
. causes of death

These matters are treated more extensively in section 1 2.4. ; where such transfered data is to be held in a central register, it will be further handled in section 5.1.

1.2.4. Rules concerning the transmission of personal information

a) Transmission to assure the continuity of treatment

The necessity of assuring continuity and quality of treatment frequently obliges doctors from various medical disciplines to share information. We refer here to the rules and limitations, reserving for section 2.1. those relative to the obligation to professional secrecy with regard to third parties.

Every doctor is required, upon the patient requesting or agreeing to it, to communicate to another practitioner designated by the patient, all necessary and useful information concerning him of a medical or pharmaceutical nature. This arrangement applies to all practicians in the curative sector (doctors, dentists, pharmacists) (10).

According to the code of medical ethics, a doctor decides when and how much data he should pass on, taking into account his oath of secrecy (11). The nature of information is decided by the nature of the treatment or examination to be carried out, or by the patient's situation ; thus, when a patient transfers his confidence to another doctor, the complete file may be transfered. This is diminished in the case of hospitals, where a ministerial circular requires them to maintain a record which must remain at the disposition of the medical staff against the possibility of a readmission (12). In the area of home care, only such data as is strictly necessary to ensure the continuity of treatment should be communicated to nurses (13).

A ruling may foresee an obligation to transmit results from a preventive practitioner to a curative one designated by the patient and, assuming the agreement of the person concerned, to another preventive practitioner (other than a doctor in occupational health care) (14).

b) Transmission for the purpose of protecting the financial rights of the patient

In order to proceed with the payment of care or the reimbursement of costs accumulated by the patient, a certain amount of information must be communicated to the health insurance institutions involved ; certificates of treatment and prescriptions must bear the patient's full name and the code of the service supplied (diagnosis, treatment, medication, ...) (15).

In certain cases, a special authorization mentioning the diagnosis is required from the consultant doctor of the health insurance system with a view to ensuring the repayment of certain treatments or securing the right to certain indemnities such as invalidity compensation.

According to the code of medical ethics, the family doctor must, at the request of the patient, transmit to the doctor assigned to give an expert opinion, such information as will assure the rights of the patient (16). Clearly, the agreement of the patient is essential, and its absence prohibits any form of transmission upon the sole demand of an insurance institution (for example, life insurance).

In principle, information gathered by the inspecting doctors of the INAMI (National Institute of Health and Invalidity Insurance) in the course of administrative procedure is subject to the oath of professional secrecy. This applies to all the civil servants of the medical control service, as they are sworn officials. However, it must be remarked that, where enquiries have been made, information has sometimes been found to circulate among non-medical personnel, for example in administrative and judiciary departments, despite a ruling that the passing of medical information may not entail the movement of documents necessary to the exercise of the mission of control (17). One has reason to fear violations of secrecy in such cases, despite certain legal guarantees designed to prevent the same (18).

c) Right of society

In certain cases, society takes protective measures for the persons concerned and for third parties. Thus, in the case of the confinement of the mentally ill, for which a certificate is required, largely to diminish the chance of abuse. As regards the obligation to produce certificates of birth or death, such a measure of general order enforces the right of each individual to a share in society and assures his protection and the respect of his civil rights.

In the area of health insurance regulations, the control of the services and of the sums paid out of public funds entails a right to survey the activities of practitioners, notably in the matter of repayment of sums not owed. In this matter, certain practictioners, (e.g. radiologists and biologists) must keep the prescriptions addressed to them and submit them on demand to the entitled authority, for example the medical control service pertaining to the health insurance.

d) Transmissions for reasons of public health

In cases where the doctor diagnoses a venereal disease, he must address a report to the hygiene inspector, mentioning the nature of the disease, the commune in which the patient lives, as well as the name and address of the person considered as the source of the infection (19). He may not, however, identify the patient who has consulted him.

Reporting to the health authorities may also be made obligatory with a view to preventing the propagation of certain epidemic diseases (quarantine illnesses, those subject to international declaration or certain other transmissible illnesses) (20).

Those responsible for the inspection of convalescent homes may verify that each resident possesses a certificate attesting that he is carrying no contagious disease (21).

e) Health statistics

The admission of patients to a hospital must allow the breakdown of the patients according to the commune in which they live (22).

In the case of the registration of births, it must be mentioned whether the child was stillborn, lifeless at the time of registration or alive (23).

2. OBLIGATIONS TO SECRECY

2.1. General principles

2.1.1 Respect of privacy

The European Convention on Human Rights and Fundamental Liberties recognizes a right to the respect of privacy (24)..

2.1.2. Professional secrecy

"Doctors, surgeons, health officials, midwives and all other persons who by profession or estate are the depositories of secrets confided to them" ... and who reveal such are punishable (25). Two exceptions are foreseen : testifying in a court of law and the communication of information imposed by a law (cf section 1.2.).

According to R. GROSEMANS, the dispositions of article 458 of the penal code apply indistinctly to any person invested with a confidential function constituted by law, tradition, or morality (26).

Without being directly cited, nurses are also touched by article 458 of the penal code. In the case of social workers they are equally held to professional secrecy because, according to R. GROSEMANS, "it would be dishonest and thoughtless to betray the confidence of the patient or his family through the airing of secrets confided to a social worker" (27). In our opinion, they are equally the depositories of "secrets confided to them" and therefore punishable should they reveal them to the detriment of the patient. One must of course take into account that the accomplishment of their mission demands at certain moments the sharing of certain secrets in order to assist in resolving the problems upon which they have been consulted ; their situation is therefore ambiguous. It becomes even more so when one considers that some of their functions permit them access to information, not in the form of "confidences" imparted by the patient, but in the way of inquiries which they are obliged to make in order to establish the patient's rights to certain social advantages. Usage permits therefore the communication of information necessary to the establishment of the patient's rights or its rejection in the event of the situation not conforming with current requirements or laws. In any other context, the rule must be the respect of professional secrecy.

Professional secrecy bears not only on the confidences of the patient, but also applies to everything the doctor has seen, noted, learned, verified, accidently discovered during or as a result of examinations or investigations, whether while exercising or as arising from the exercising of his profession (28). Common usage tends to extend this definition, which was developed within the framework of the medical profession, to all health professions.

2.1.3. The shared secret

As to other professions, (for example secretaries, ...) who may have access to certain information relating to the patient, it is unanimously understood today that hospital directors and administrative staff (including technical) are subject to article 458 although not expressly cited in the penal code, by reason of the fact that they are obliged to collaborate with those who are (29).

Moreover, the code of medical ethics obliges a doctor to assure the respect of his oath by his collaborators (30) ; such is the principle of the "shared secret" (31).

Specific regulations have been prescribed by the Order of Physicians in that which concerns the protection of the confidential character of electronic data (cf section 3.3.). The concept of "shared secret" only applies to transmissions of medical information to other qualified people who are themselves held to secrecy and only with a medical motive and within the limits of the organization of treatment (32).

The shared secret, like the professional secret, is a notion established in favour of the patient. Recent controversies about information relative to seropositivity and AIDS have shown that the sharing of secrets cannot be allowed as a means to protect personnel ; thus, in certain laboratories, it is the custom that only the doctor attending to the dossier knows the result of an AIDS test.

2.1.4. The obligation to discretion

In the terms of the law of employment contracts, a worker is obliged to abstain, whether during the duration of his contract or after its expiry, from divulging ... the secret of any matter of a personal or confidential character which has been made known to him in the exercising of his profession (33).

2.1.5. Sanctions for violations of secrecy

The professional secret by which doctors are bound is regulated by a code of medical ethics (34). This code has no force of law ; however the bodies responsible for its enforcement (the provincial Councils of the Professional Order) are legally authorized to apply disciplinary sanctions, which may be more heavy than those the offender would incur in a penal case ; they may go so far as to bar the offender from practising his profession.

Other than doctors and pharmacists, other health care professionals are not subject to the authority of a professional Order.

It is up to the doctor to see that the secrecy to which he is legally bound is observed.

Divulgence of a secret may be a sufficient motive to break a contract of employment on grounds of grievous fault.

Before arriving at such extremities, provisions for sanctions against health care personnel or other ancillary professions for violations of secrecy or indiscretion may already be made part of the working relationship, for example in the contract of employment or working regulations (see particularly section 3.3.3.). Thus, a law from 1965 introducing working regulations, contains arrangements relative to

penalties, the sums involved, the destination of such fines, as well as the lapses they are intended to sanction (35) ; only penalties foreseen by the rules of work may be applied (36).

Such clauses are relatively rare in hospitals ; the private sector hardly knows of codifications, analogous to those planned for disciplinary systems applicable to employees in the public sector. In order to be applicable, rules of this type must first be negotiated with representatives of the workers. They might foresee, for example, that lapses of duty which, for the employee, are specified in his contract and which are not of sufficient gravity to justify an immediate dismissal without compensation, should be punished in the following manner :

- a formal summons,
- a fine between ..... and .....
- an exclusion of one or more days without pay or compensation.

To summarize, working people involved in the organization of health care are held to secrecy and may, in the case of a violation, be sanctioned in one of the following ways :

- their own ethical code, sanctioned, in such cases, by a professional Order ;
- the terms of the employment contract, governed by the law on work contracts, which imposes the obligation to discretion and the non-fulfilment of which may lead to disciplinary action or even immediate dismissal without compensation in the event of grievious fault ;
- should the occasion arise, the rules of work (which must fulfil certain formalities) may provide for various sanctions against workers who violate the rule of secrecy.

2.2. Particular cases

a) As regards hospitals, one may well ask who is finally responsible, thanks to a relatively new and confusing code of hospital law which from now on differs from medical law. One may suppose that there is currently a deplacement of responsibilities to those new authorities envisaged by the code of hospital law, notably the head doctor (37).

Thus, the Ministry of Public Health expects the head doctor to be responsible for any necessary measures to be taken in organizational restructuring in order to guarantee the confidentiality of medical files and archives (38).Special precautions are planned to guarantee discretion in the use of electronically processed files (cf section 3.3.)

b) Officials charged with the inspection of convalescent homes may have access to a file indicating the directives of the "preferred" physician and their execution ; there is no access to actual medical records (39).

c) The law relative to the Social Security Clearing Bank (which organizes the means of communicating certain social data between the diverse Social Security institutions) submits all personnel to an oath of professional secrecy who, by reason of their function, participate in the collection, treatment or communication of social data of a personal character, or have knowledge of it (40).

3. AUTOMATED MEDICAL DATA BANKS ; THEIR AUTHORIZATION, LIMITS AND PRECAUTIONS

3.1. Authorization

According to a draft bill, medical data of a personal character are to be distinguished from purely administrative health care data. The former may be processed under certain conditions. The latter may, even without the specific written consent of the patient, be electronically processed by a doctor so long as the access is confined to himself, his substitute, his successor or their medical team (41).

This option is implicitely recognized by international accord (42) while specifying certain limitations with regard to sensitive data.

The limits of this freedom or dispositions to the contrary are mentioned below and notably in section 3.3.6.

3.2. Limitations

A series of rules and recommendations endeavours to protect the privacy of the individual in the face of the potential dangers involved in data processing.

a) At the international level, several accords have been enacted for the protection of privacy ; within the Council of Europe and within the framework of the O.E.C.D. (43).

Belgium is not legally bound by these accords, but she has nonetheless signed the Convention of the Council of Europe of 28.1.1981 for the protection of the individual with regard to the automated processing of personal data. She has not yet ratified this, neither does she yet dispose of a national law on this matter.

Nevertheless, the Recommendation of the Ministerial Committee of the Council of Europe relative to medical data banks (44), although devoid of normative force, is of particular interest within the framework of the present study (45) ; we shall refer to it in our conclusions.

b) Under the law of 15 January, 1990, respect for professional secrecy is restressed ; those who in the nature of their function participate in the collection, treatment or communication of social data of a personal character or have knowledge of the same, are required to respect their confidentiality (46).

This law accentuates above all the structural protection of data, contrary to certain foreign legislation, German or Danish for example, which concern themselves more with enunciating the material norms of security (47).

c) A consultative commission on privacy has been created within the framework of the law organizing a National Register of individual entities (48).

d) In a more particular domain, the Order of Physicians considers that the medical record of a company doctor may not be stored in the central computer of a large company, because professional secrecy cannot be sufficiently guaranteed (49).

3.3. Precautions aimed at guaranteeing the confidentiality of data

3.3.1. Designation of a responsible person

In hospitals, the doctor responsible for electronic data files must enjoy the full confidence of the Provincial Order of Physicians. The doctor responsible is the guarantor of the confidentiality of the data (50).

Social Security institutions must designate a doctor under whose surveillance and responsibility the processing, exchange and communication of personal medical data may take place. The identity of this doctor must be communicated to the authorities in charge of the information system (51).

It is important to guarantee the independence of each administrator of a social security data bank. According to D. Pieters, in a commentary on the Belgian draft bill, this independence is insufficiently guaranteed, compared with the regulations for "intern Datenschutzbeauftragte" current in Germany (52).

3.3.2. Limited access

a) Medical data in the Social Security network

According to the law, individual entities who may record, consult, modify, process or destroy personal medical data are designated by name. The content and extent of their authorization of access are defined and recorded in a register which must be kept regularly up-to-date (53).

Access to medical data kept in automated social data banks should be subject to the use of individual codes of access and competence. The bearers of such codes may not divulge them to anyone (54).

The communication of information to third parties may only take place at the insistence of the Central Clearing Bank and according to strict regulation (cf section 3.3.4.) ; meanwhile, waiving this general principle, transmission may be made directly to those whom the persons concerned have expressly authorized ; the latter must take place in writing and may stipulate a maximum duration of validity (55).

b) Emergency card

With regard to medical emergency cards (regulated by the Flemish Community), the introduction or modification of information covered by medical secrecy may not be made, except through use of a card reserved for the patient's family doctor in combination with the patient's own secret code (56).

According to the Order of Physicians, it is difficult to establish an exhaustive list of doctors permitted to share medical secrets, since a certain number of them occasionally serve as experts, which disqualifies them from sharing medical secrets (57).

This objection being well-grounded, it results that :

- either the medical data card may never be obligatory ;
- or it may only contain typological data (for instance, blood group) without mention of pathology, losing thereby a considerable part of its usefulness in an emergency ;

- or the card is reserved solely to a group of practitioners who know one another and can therefore be safely identified ; its use as an emergency card or synthesis file or otherwise, is thereby restricted to the members of the group ;
- or the card constitutes a synthesis file accessible with the authorization of the patient (password) ; here again, it loses its value in an emergency if the patient is unconscious ; furthermore the risk of pressure being put on the patient cannot be excluded, particularly in the case of applying for employment;
- or, the statute of expertise should be rendered incompatible with that of treatment, which seems illusory and hardly rational.

In the event of the use of the card expanding (all the more so if it becomes obligatory), it would be doubtless opportune to include in the code of medical ethics a new rule prohibiting doctors to access the card while working in the framework of a mission in counsel, expertise, control or other official function.

c) Medical files in hospitals

As regards minimum basic data sets, any user of electronic medical files must be identified and controlled ; a list of persons (doctors) authorized to have access to files must be established and kept up to date (58).

3.3.3 Obligation to discretion

According to the Order of Physicians, personnel working in the information unit of a hospital must come under the direct authority of the doctor in charge of data processing and be subject to article 458 of the Penal Code (which punishes all transgressions of professional secrecy) (59).

The question is to know whether article 458 may be applied to them, inasmuch as the confidence reposed in them is not the act of the patients, but of doctors who are themselves depositories of the secret ; on the other hand, it is possible to interpret the notion "confided to them" as including that confidence reposed in them by the depositories of the secret, obliging them to shared secrecy. It is currently admitted that collaborators of persons bound to secrecy are themselves equally bound (cf section 1.2.3.).

Furthermore, as we have noticed, the general law on employment contracts imposes a general rule of discretion. It would be highly desirable to repeat that obligation in the wording of the employment contract and furthermore to require a signed engagement to respect the professional secret (sanctioned by article 458 of the Penal Code) and engaging the signatory to assume the obligations and responsibilities that may devolve upon him through the application of these rules. Workers must furthermore commit themselves not to communicate, whether within the duration of their contract or afterwards, any information, document or electronically processed data which has not formally been made public. A similar initiative was introduced elsewhere with regard to student trainees of the Law Faculty of the Free University of Brussels.

3.3.4. Limits to the possibilities of data transmission

In the area of Social Security, the law of 15 January 1990 provides that any communication of personal data of which a Social Security institution or the Central Clearing Bank (which records the nature of available information and its location) is the source must formerly have received an authorization in principle from the watchdog committee which verifies whether the requirements fixed by law, by internal regulation and by the management committee of the Central Bank, relative to the transmission of data, have been fulfilled (60). The watchdog committee keeps an up to date inventory, which is accessible to those interested (61). According to D. PIETERS, commenting the draft bill, the Central Bank is thus charged with permanent control, and can go as far as to prohibit a transfer if it is shown to be illegal or not to fulfil the necessary guarantees (62) determined by the King.

Sanctions are foreseen in the case of persons who request and obtain personal data for which they have no need within the framework of Social Security work (63).

According to D. PIETERS, commenting on the draft bill, the determinant legal criterion for authorizing transmission of personal social data is that of "need". Certain foreign legislations are more strict in this matter and demand a certain "equivalence" or proportionality between limitations on that which is considered private and the "needs" of administration. It is in this sense that D. PIETERS pleaded for the use of the word "necessity" to replace the word "need" and was astonished that there was no control of the "advisability" of the transfer (64) (65).

3.3.5. Consent and/or notification of the patient

The Council of Europe considers that the patient should be kept informed of data gathered concerning him and of the purposes it serves (66).

In Belgium, informing patients of computerization of their medical file, its use and the purposes of any research is not obligatory except in the case of specific legislation.

The Belgian draft bill on privacy stipulates that as soon as access to personal medical data ceases to be reserved to those health care professionals specified by the text (cf section 3.1.), the person concerned must indicate his consent in writing before appearing in personal data programmes relative to his state of health, to medical examinations, medical care, or treatments for alcohol or other toxic dependence (67).

Moreover, in that which concerns the standardized medical emergency card, particular problems are posed by reason of its portability and the possibility of access in various health care localities. The Flemish Community prescribes that the bearer should be in agreement if the card is to contain his identity, his identity card number, factors that could endanger his life and information necessary for effective treatment in case of emergency, such as mortal risks (68). The National Council of the Order of Physicians considers that this ruling does not offer sufficient guarantees (69). According to the Council, the patient should have a perfect right to require the recording doctor to omit certain matters from an emergency card and they mention specifically alcoholism, AIDS, schizophrenia and drug addiction. In France, on the other hand, certain sensitive data are excluded from the emergency card, failing the written authorization of the bearer.

3.3.6. Nature of information

a) Sensitive data

Certain data are considered as more "sensitive" (71) as, for example, a person's ideological or political orientation. International accords enjoin prudence in this matter. Thus, in that which concerns the use of personal data for Social Security purposes, the Council of Europe proposes that data concerning racial group, political opinions, religious convictions (72), sexual habits and health should not be authorized for collection or treatment as long as the internal regulatory laws do not include the appropriate guarantees (73). We can deduce from this, that a system of legal guarantees must surround the processing of data.

The Belgian draft bill for the protection of privacy takes up this distinction by envisaging only restricted processing of such data, even if the information is considered useful to medical treatment.

In this sense, even the membership of a particular health insurance, reflecting as it does in Belgium a certain ideological character, could be considered as sensitive and subject to precautionary measures in the framework of Social Security data processing to assure that such information does not appear in the Central Clearing Bank. The same idea is taken up in a more general way within the draft bill as the protection of privacy proposed by Minister Wathelet.

In the medical domain, other data is sensitive inasmuch as it constitutes, in its entirety, information capable of being used for the purpose of exerting influence upon sick people. One may cite, for example, the information that the National Council of the Order of Physicians proposes to omit from the emergency card (cf section 3.3.5.), such as alcoholism, drug dependence, mental illnesses, seropositivity in AIDS testing. In our opinion, these could be included, even in a personalized record, on the condition that such be held only at the practice of the "preferred" physician or family doctor.

b) Information that endangers anonymity

Precautions are often necessary to ensure the anonymity of information gathered together in larger quantities. The question arises notably with regard data that can be indirectly personalized within the framework of national registers or anonymous data bases (cf sections 5 - 7) ; we are concerned here with information that is theoretically anonymous, but which, in conjunction with other data, nonetheless risks identification with an individual.

We mention, in this regard, a recent controversy over death registrations, which are obligatory (cf section 5.3.). In the matter of the death of young children, the scientific association of obstetricians has suggested that information giving details of the maternity clinic be added, in order to permit them to compare their results with regional averages. Nevertheless, the National Council of the Order of Physicians considers that anonymity could not be guaranteed and has therefore given a negative opinion on deontological grounds (74).

3.3.7. Keeping information up to date ; rights of interested parties to verification

International accords foresee the right of the individual to have access to personal social data concerning him (75). However, the specific character of medical data is recognized and it seems to be admitted that countries could restrict the right to obtain or rectify medical data deemed as necessary to scientific or statistical research (76).

The quality of data is important in this area and the Convention of the Council of Europe specifies that such must be exact and kept up to date (77). This responsibility devolves upon diverse health care practitioners, the "preferred" physician and the programmer directing the cataloguing of data.

In Belgium, the law of 15 January 1990 demands that Social Security institutions communicate to all beneficiaries, or their legal representatives, their personal social data, establishing their rights (78). The law furthermore obliges them to correct any inexact data and to erase such data as may be superfluous or obtained illicitly or in an irregular manner (79). The Clearing Bank contracts to communicate all corrections or effacements to all Social Security institutions concerned (80).

3.3.8. Time limitations

According to the Council of Europe, data may not be conserved beyond the legitimate finalities of treatment. Does this refer to the entire life of the patient? And beyond this, does epidemiological research justify the conservation of anonymous data?

Personal data may not be conserved by a social service institution for longer than is justified by the task at hand or the interest of the person concerned (81). If further conservation is useful to scientific, historic or statistical research, such data should if possible be rendered anonymous (82).

3.3.9. Code of conduct

There exists no legislation imposing upon those responsible for data banks the duty of drawing up a code of conduct or of submitting themselves to the approval of a higher authority. In this, Belgium differs from certain foreign countries, for example Denmark (offical ratification of codes of conduct) or Holland (publication of such codes and notifiction of the special Chamber). Nevertheless, according to D. PIETERS, commenting the draft relative to Social Security data banks, articles 22 and 23 seem to already announce the elaboration of such codes of conduct as are appropriate to each institution and adapted to their particular needs and risks (83). These codes may provide for disciplinary measures.

4. TRANSMISSION OF INFORMATION BY TELECOMMUNICATION

4.1. General principle : protection of privacy

According to the Belgian draft under discussion, it should be forbidden to persons directing computer programmes containing medical data (state of health, medical examinations, medical care, treatments for drug dependence), to communicate data of a personal nature to a third party without the specific written consent of the patient, except to another doctor and "in case of emergency" (84).

In our opinion, this last precaution is without doubt extreme if it imposes a supplementary condition of urgency on any transmission ; if it were interpreted as the right to transmit to any third party "in case of emergency", it must be evaluated according to the nature of the emergency. In that which concerns collections of processed data, may one not recommend the following :

- the transmission of personal medical data to third parties is prohibited, except to the "preferred" physician, the family doctor, and to the practitioner's team charged with the care of the patient, within the necessary limits of the treatment and its follow-up ;
- before transmitting data from one terminal to another, the practitioner in charge of the case must ask for the written consent of the patient, which document should contain the name(s) of his family doctor and if necessary, of the "preferred" doctor designated by the patient.

This precaution would be obligatory for any system transmitting via network or modem. On the other hand, transmission via courrier or a data carrying medium (floppy-disk or eprom) need not, in our opinion, entail such precautions, since the risks involved are not greater than in the case of paper correspondence (indeed, they may be less, since a supplementary technical barrier exists).

4.2. Examples of authorization for personal data

The transfer of a medical record from one company doctor to another, when a worker changes filiale or department within the same firm, may take place by computer, as long as the company doctor takes the necessary precautions for the proctection of professional secrecy (85).

If the worker is engaged by another firm, the transfer of his file may take place with his approval and with respect for professional secrecy (86). Nothing has been specified with regard to an eventual transfer from one computer to another.

5. EXAMPLES OF CENTRALIZED INFORMATION REGISTERS COMPOSED NOMINATIVELY

5.1. Local registers of diseases subject to compulsory declaration

Every mayor must keep a register containing the declarations he receives of transmissible diseases (87).

5.2. Register of congenital abnormalities

Approved centres for the tracing of diseases and congenital metabolic abnormalities must establish a nominative list of infants concerned :

- the list must be accessible to doctors designated by the Minister of Public Health ;
- a nominative review of abnormalities must be sent to a doctor attached to the superior Council for human genetics (88).

5.3. Declaration and registration of deaths

Reports of death made out by the Registrar, give the name, forename, address, place and date of birth, name and forename of spouse, and civil status (89). Doctors are required to declare the cause of death. In cases of infant deaths, he must record the birth weight, duration of pregnancy, eventual defects as well as certain family characteristics : profession, nationality, civil status and birth dates of the parents, time span between the last two births and number of other children.

A special administrative register lists still births and those dead at the time of registration, indicating the distinction (90).

5.4. National AIDS Register

Within the framework of the fight against AIDS, a form has been developed to indicate known AIDS cases. The forms contain nominative identification data and are sent to the superior Council for coordination of the campaign against AIDS. The president of the Council must detatch the part of the form containing nominative data. At the headquarters the data must be separated. Identification data and medical data are recorded on separate floppy-disks. The identification data includes date of birth, sex, civil status, nationality, ethnic origin, address and profession as well as the probable means by which the disease was transmitted. In the absence of a supplementary basis in law, personalized data concerning ethnic origin might pose problems if the draft bill for the protection of privacy currently under discussion were to be approved.

5.5. National Cancer Register

Each national health insurance federation identifies those of its affiliates presumed to have cancer and records confirmed cases on computer. At this stage the patients are perfectly identifiable. The sum of data is then communicated to the national level. The national Cancer Register thus created has obtained authorization to access the national population register, thus using the national number to avoid double entries and in order to correct any patient data which may be inexact. The consultative commission for the protection of privacy has authorized such access on condition that :

- the National Register number be recorded in cryptic form ;
- by information recorded in long hand, a distinct number should be used and the conversion table between this number and that of the National Register should also be in cryptic form ;
- the National Register number shall never be communicated to those providing or transmitting the data ;
- only those working at the Cancer Register may use the national number in the framework of their work and according to their competence ; such persons must be designated in writing ;
- data from, and the number of, the National Register may only be used for means of identification ;
- the National Register number may not be used by the Cancer Register in its relation with third parties.

6. EXAMPLES OF DATA BASES FOR THE PURPOSES OF ADMINISTRATION

6.1. Care at the hospital : minimum basic data sets

During a test period, hospitals must communicate, by magnetic medium, general data relative to the institution, data on care provided, and data concerning the patient (year of birth, sex, date of admission, date of discharge, principle diagnostic code ICD-9CM, complications) (91).

In order to preserve the anonymity of information in the event of integration, only the year and not the date of birth are mentioned and a number specific to the patient is given within each hospital, so that, according to a circular from the Ministry of Public Health, only the doctor on the case and the ward nurse know the name of the patient (92). This assurance is probably premature, since it is nowhere required that the doctor and nurse expressly cited are expected to personally see to the distribution of patient numbers ; taking into account the work load of nursing staff, one may imagine that such a task would frequently be given to co-workers.

The question is to know which information could enable a patient to be identified. In this framework, the National Council of the Order of Physicians considers it permissible to supply the identification number of the hospital and department, the sex and year of birth of the patient, the length of his stay and the nature of entry and discharge, diagnostics and particular treatments or techniques ; on the other hand, the Council disapproves any numeration other than sequential or aleatory, and refuses therefore any administrative number, of hospitalization or of National Register, as well as identification data, such as name, forename, date and place of birth, place of residence, date of entry and discharge from hospital or the dates of operations, treatments or technical measures (93).

6.2. Minimal summary of nursing care

Hospitals are asked to communicate a minimal series of medical and administrative nursing data to the Ministry of Public Health (94).

Such data includes intimate data about the patient, such as the level of dependence and the ability to manage the general activities of daily life (feeding, hygiene, mobility, ...), incontinence, psychological defects, habits, as well as self-care such as intimate hygiene or the ability to control emotional crises.

The remarks concerning risks relative to the identification of the patient and the precautions to be taken are the same as for section 6.1.

6.3. Monitoring of the length of stay

In order to monitor the length of stay (whose payment varies with time for long term illnesses), hospitals had to deliver, for each trimester of 1987, the patient's individual number, sex, age group, personal situation (with or without partner, cohabitant or not, with or without house care), as well as the diagnostic code (ICD 9-CM) (95).

6.4. The Social Security Central Clearing Bank

This bank, called into being by the law of 15 January 1990, has, among others, the mission to collect from Social Security institutions information useful to the understanding, conception and management of Social Security. This collection may only make use of data which has been depersonalized. The establishment of representative samples, destined for the same ends, will also be authorized under conditions that have yet to be defined (96).

The production of such anonymous information often first requires that data concerning the same person, dispersed through different Social Security institutions, be combined ; it is the task of the Central Clearing Bank to depersonalize the data it has requested from various institutions once it has been reassembled.

7. THE CASE OF DATA BASES FOR EPIDEMIOLOGICAL PURPOSES

7.1. General principles

A doctor may make use of his medical files for his own scientific research, on the condition that he does not allow any names or personal details, that might permit the identification of a patient by others, to appear in his publications (97). He may also communicate his findings to scientific institutions, but only in anonymous form (98).

A doctor is obliged to provide the information he possesses in the event of being required to assist in the production of public health statistics, measures being taken to assure the anonymity of such findings (99).

The storage of medical data in a central computer for the purposes of epidemiological research, may not take place except with such data as is strictly necessary for the study, shorn of all elements permitting any kind of identification (100).

The correspondance between anonymous minimum basic data sets and the identity of patients are held by the doctor in charge of programming in the form, for example, of a sequential exit number and a number chosen by hazard (101).

The attribution of numbers to patients should be realised by a system of codification which hinders double entries without in any way permitting the patient in question to be identified by name (102).

7.2. The network of sentinel doctors

A certain number of doctors, about 150, participate monthly in an epidemiological enquiry on specific health problems. The forms used respect the anonymity of the patient, identification being only possible by the doctor concerned. The forms require a certain amount of personal information describing the patient : age, sex, type of cohabitation or household structure and certain information specific to the problem under survey, for example, level of autonomy, concentration and speech defects, incontinence, risk factors such as smoking, sexual partners and particular features of sex life, ...

7.3. Network of microbiological laboratories

Continuous monitoring of infectious diseases is assured thanks to the participating laboratories, which register each month a certain number of findings : micro-organisms concerned and, in each case, the age and sex of the patient, the type of sample, the diagnostic method used, details about the patient, (for example profession), if such could be of use to the advancement of knowledge about the disease.

CONCLUSIONS

In our country as in others, draft bills and laws are practically dumb on the subject of computerized medical files. Even though some within the profession argue for the defense of the privacy of the patient by utterly opposing any computerization of the medical sector, such a position appears to us anachronistic at a time when the computer is leaving the restricted circle of professionals to become a tool of an ever widening section of the general public.

Beyond that, computerization of medical data enables the attainment of numerous objectives : improvement in the quality of care ; the development of epidemiological knowledge, based on actions founded in the domain of public health policy ; better management of health care systems with a view to more effective administrative and fiscal policy (for example, in the area of Social Security reimbursements).

Nonetheless, the fears of abuse or piracy of data oblige the provision of a number of guarantees whether regulatory, penal or deontological. The aim of such measures is to preserve the right to privacy of the patient, but, beyond that, to effectively asserve respect for his liberties, such as the liberty to attain bank credit or employment, which could be endangered by the divulgence or illegitimate handling of medical data.

Our intention in this conclusion is to examine the guarantees which should be set up in the field of medical data flow. To this end we shall make use of two conceptual tools, representing two types of data defined within the framework of European research programs : the minimum basic data set (MBDS) and the patient related data set (PRDS). The former, a summary of a contact between a patient and a practitioner, is designed to standardize data transmission ; the latter, to standardize the personal profile of the patient (103).

These data sets may be the object of various forms of processing :

- firstly, restricted to a medical team ;
- secondly, a wider shared use spread throughout an information network, or accessed through the medium of a shared service center ;
- thirdly, in the framework of medical research or management of the health system ; in such cases, data banks are usually anonymised (except in the case of certain specific research).

have the right to verify the exactitude of personal characteristics, (e.g. age, sex, household structure, ...) not, however, medical, social or psychological data. These must be communicated to him on demand by a doctor, but corrections he may demand will not be considered obligatory
if they are contrary to the medical, psychological and social situation as observed.

B. The enlargement of organizational, ethical and legal guarantees relative to professional secrecy

The first guarantees with which we are concerned are those of a technical and organizational nature directly touching the electronic data systems used by health-care professionals ; the systems should be protected in the light of guidelines already current in hospitals : access restricted and modulated (certain parts accessible only to certain professions), individual codes of access and competence, lists of authorizations-to-access kept up to date and sent to a central body, "signing" of such consultations and management of such access with a view to eventual verification. Security standards could be developed for use with data banks and programmes in the medical sector. The conformity to such standards could be verified and conforming systems awarded a label of quality.

Beyond these first guarantees, certain others could be found within the code of ethics. The code of medical ethics, which already imposes upon doctors the obligation to see that medical secrecy is respected by their assistants, should match this 'obligation of result'to an 'obligation of means' by requiring their co-workers to sign a document binding them to respect shared secrecy.

It would be useful if clauses relative to respect for professional and/or shared secrecy were introduced clearly into all employment contracts, as well as business contracts (binding independent contractors and ancillary service companies).

Hospitals should enter into negotiations with their employees' representatives, in order to introduce into the rules of employment, graded penalties that would serve as a firm reminder of the obligation to professional secrecy, without being driven to dismissal as the only recourse.

Meanwhile, problems exist, as much in hospital as in ambulatory care. The prospect of computerized data calls for supplementary precautions, on account of the vulnerability of such files and the dangers of abuse in case of robbery. Consequently, the following recommendation might be envisaged on the level of legal guarantees : article 458 of the Penal Code sanctioning respect for professional secrecy should be more clearly extended not only to any person who by status or

The following reflexions revolve around these three types of processing.

I COLLECTIVE SETS OF PERSONALIZED DATA WITHIN A MEDICAL TEAM

Three questions must be dealt with :

- the legitimacy of information processing by a physician in attendance ;
- the enlargement of organizational, ethical and legal guarantees relative to professional secrecy ;
- precautions, including the permission of the patient, in the event of transmission between physicians on the same case.

A The legitimacy of information processing by an attendant physician

The doctor who keeps a medical file is free to choose a medium, even without the consent of his patient, on condition that access is restricted to himself, his replacement, his successor and their medical teams.

In that which concerns the nature of the data, a doctor is free to indicate in his personal files, any data he judges to be useful to treatment or epidemiological analysis, even if such could be considered sensitive. Thus, where certain socio-economic data (such as profession, habitat, race) could have an influence on health, it would seem useful to us that their inclusion be authorized.

The permission of the patient should not have to be established in writing in the case of files opened and processed by his own doctor ; for sensitive data, such as alcoholism, drug-dependence, schizophrenia, because these are important medical aspects when taking on a patient, it should be possible to include them in a doctor's file.

In that which concerns the verification of content, a right accorded the patient in draft bills on privacy, a problem arises with regard to medical data, inasmuch as a doctor includes in his files, hypotheses, interpretations, personal notes which he does not necessarily wish to open to the patient ; it is furthermore true that, in the case of grave illnesses, the communication of a disturbing truth, if injudiciously handled, can cause more harm than good to the sufferer. We recall the prudence of the Code of medical ethics in that which concerns the revealing of grave diagnoses. It is therefore appropriate to apply a particular ruling here : the patient will

profession is a depository of secrets confided to him, but also to all those who by status or profession are susceptible to have, or might be led to have, knowledge of such secrets. The obligation to professional secrecy would also be formally extended to cover the indirect case of "shared secret", more particularly applicable to medical secretaries and programmers, not only those attached to a medical team but also those of exterior contractors responsible for set-up or maintenance of medical data systems.

C. Precautions to be taken in the case of transmission between health care practitioners

One may distinguish transmission to the "preferred" or family physician from that which may take place towards or between other practitioners (e.g. consultants dealing temporarily with the case, or practioners assuring the continuity of treatment).

All medical data should be transmitted to the "preferred" or family doctor, who thereby becomes the central axis of information on the patient. A general obligation exists here and now to transmit to the physician designated by the patient, any information useful to the following up of treatment. We note that the same is not true of other countries. Thus, Danish law restricts medical information destined for the "preferred" physician.

In that which concerns the nature of data destined for other health care professionals, the rules of usage apply : "all information, medical or pharmacological, useful and necessary to the case" ; to the degree that social or psychological data are useful to treatment, one may assume, with reference to the spirit of this rule, that they are transferable. The doctor transmitting must judge the pertinence of this or that data to the treatment prescribed or intended before communicating them. A computer trace of such a transmission should be kept.

Should there be a written consent before data is transmitted to a "preferred" physician or from him to his team?

- Certainly not for MBDS, which are analogous to examination protocols sent to the doctor or communications designed to coordinate the care of a home treatment team.

- The question is valid with reference to PRDS, inasmuch as a patient might wish to start his file at zero, without all the embarrassing details of his past history, whether domestic or professional, being transferred ; here written agreement would be preferable.

In any hypothesis, two security rules should be proposed :

- If the telecommunication of information is authorized, it should be surrounded by guarantees based on those already in use in hospitals, such as : designation of a doctor in charge in clinical laboratories, establishment of security procedures. Transmission by mail of floppy-disks or EPROM should be authorizable, given also certain conditions such as : right to access limited solely to doctors, obligaton for health care practitioners to "sign" the contents of the message ;

- data introduced or corrected by a health care professional other than the "preferred" doctor should be "signed" and dated.

II CENTRALIZED INFORMATION SYSTEMS SHARED BY VARIOUS MEDICAL TEAMS

For groups of doctors working together or making use of a shared service centre charged with data processing, as well as for a hospital or a group of clinics making use of the same data base, specific rules, other than the precautions described above, should be devised to prevent fraudulent use or abuse. One may usefully be inspired by the recommendation of the Council of Europe, signed by the European Ministers, and relative to data banks, notably the nomination of a doctor responsible for computerized data.

To this recommendation, of which the object is specific, one must add, according to the very principle of the recommendation of the Council of Europe, the obligation of a rule (or several distinct rules where a data bank contains sub-systems) concerning :

- the purpose (e.g. clinical, epidemiological and administrative),
- the categories of information recorded ;
- the types of persons authorized to access, record or modify the data ;
- the conditions under which information may be communicated to a third party ;
- the procedures relative to requests to use the data for purposes other than those for which they were gathered ;
- the conditions under which, should the case arise, the data bank may be interconnected with other data banks.

The same recommendation establishes :

- In that which concerns the means of collection, the rule already inscribed in the convention of the Council of Europe requiring :

  - collection of data by fair and legal means ;
  - collection of adequate and pertinent data with regard to the declared purposes ;
  - the exactitude (verified within the limits of the possible) of such data, and the necessity of keeping files up to date according to need.

- In that which concerns the structure of files, these must be conceived in such a manner as to enable differentiated access to medical or administrative data, and among the medical data, separate access to emergency data, all such access being restricted to authorized persons. It is quite evident that such obligations must be imposed on the designers of programmes for use in the medical sector, and that a normalization or authorization of conforming systems be foreseen.

- In that which concerns access to data, according to article 5 of the recommendation mentioned above, it must be restricted solely to doctors, in principle only to doctors actively caring for the patient (continuity of treatment) and the family or "preferred" physician. In this regard the principles already described in section I apropos transmission between doctors apply.

Access may be extended, in conformity with national law or custom, to include paramedical personnel ; nonetheless, these would only have access to such data as might be pertinent to the performance of a particular task (article 5.3), and could not make use of this access capability for purposes other than those authorized.

Finally, the principle of non-communication of medical information to persons other than those occupied in medical and health care is reaffirmed, that is to say, without making an exhaustive list, forensic pathologists, consulting physicians of employers or insurance companies, except in cases permitted by law. In any such possible event, a trace should be kept of the communication.

III DATA BANKS IN MEDICAL RESEARCH SITUATIONS

Medical research may take place on the basis of anonymity, medical information of a nominative origin being duly rendered anonymous ; this is so in the case of epidemiological or statistical research designed to determine a population at risk. On the other hand, such research may necessitate the researcher keeping track of a particular patient, which may involve the processing of nominative and even highly sensitive data.

Let us distinguish the two cases :

- the former leads us, following the Council of Europe's recommendation R(89)4 on the collection of epidemiological data from institutions of primary health care, to essentially legitimize the transmission of anonymous data if coupled with a certain number of guarantees to assure genuine anonymity (104);

- the latter may be resolved by citing certain principles from another Council of Europe recommendation n° R(83)10 relative to the "protection of personal data used for the purposes of scientific and statistical research".

A. The use of anonymous medical data by research centres

The recommendation cited above insists on the importance of establishing epidemiological data banks to serve the needs of research as well as public health policy.

It insists on the necessity of primary health care institutions collecting certain data upon such factors as "morbidity" and mortality levels, but equally socio-economic conditions, professions, behavioural and psychological factors, following a European standard ; certain minimal collective sets of data should even be systematically collected in the form of health profiles.

This data, personalized only at the local level, should then be sent to the national statistic centres. Encryption keys should be used to guarantee the anonymity of data thus transmitted.

We note, in this respect, that a system intended to guarantee anonymity in epidemiological enquiries has been developed in France (105). Data is rendered anonymous at the source. Practitioners create their own anonymous patient numbers using a non-reversible mathematical formula. It is impossible to trace the identity from the number, even to someone possessing the formula and large computational power.

However, the system has its limitations ; although the individual codes are hardly reversible, even by their developers, nonetheless, anyone possessing the programmed algorithm may, if he chooses, retrace specific data to certain individuals concerning whom he already possesses the necessary personal data. The possible level of such improper use is therefore very limited. To further diminish it, one might envisage a periodic modification of the algorithm.

Meanwhile, the regrouping of data for each patient and the elimination of "doubles" may take place in two ways :

- the concentration of information on a patient at his doctor's, who in turn sends it to a system centre in anonymous form ; this is the PRDS concept, which only becomes viable when the system is sufficiently widespread ;
- the attributing of a unique number to the patient by a sort of "Clearing Bank", which in turn communicates this number to various interested practitioners, before centralizing the data; however, this method would be at once expensive and hardly viable.

In cases where general profiles of patients or of morbidity rates should be established, on a regional or even national level, or where representative samples should be drawn for scientific purposes, a similar structure to the Clearing Bank cuild be developed.

B The use of nominative data by research centres

A number of medical research projects require the use of nominative data even though the recommendation n° R(83)10 calls for researchers to use "within the limits of the possible ... anonymous data". For such cases, the recommendation cited establishes the following principles :

- that of consent of the person concerned. For the patient, it is not just a matter of being informed of the nature of the project, its objectives and the name of the research institute involved, but equally of being free to give or decline to give the data requested without needing to justify the reasons for such a refusal and, finally, of being able to withdraw consent at any time in the process ;
- that of the limitation of the processing solely to the research purposes specified, to the exclusion of any other application. Thus the data collected for one particular research project, could not be used for another, or used as a basis for deductions relative to the person concerned, "except within the framework of the project or with the express consent of the person concerned" ;

- that of the patient's right of access to data concerning him. We note, however, that this right could be limited, notably if the data has been duly rendered anonymous (cf point A) or made the object of such protective security measures as are adequate to protect the confidentiality of the data gathered ;
- that of rendering anonymous any results in the event of publication or completion of the project.

1) Statement of Purpose and Requirements of the MBDS, Preliminary Definition of the MBDS, Project CHIC (Community Health Information Classification and Coding), Commission of the European Communities, AIM Project 1026, 1989, 24 pp.
2) Code de déontologie médicale, Ordre national des Médecins, 1975, art. 38.
3) Arrêté ministériel du 15.12.1982 fixant les critères pour l'agréation des médecins qui désirent une qualification spéciale pour certaines prestations en médecine générale dans la nomenclature de l'assurance contre la maladie et l'invalidité (M.B. 22.12.1982), art. 5.
4) Loi sur les hôpitaux coordonnée le 7.8.1987, art. 15 (M.B. du 7.10.1987, p. 14 652).
5) Circulaire du 31.3.1988 du Ministère de la Santé Publique et de l'Environnement, Administration des Etablissements de soins, adressée aux Directions des hôpitaux et aux médecins-chefs.
6) MERCIER, M., Le dossier médical, théorie et réalité - fonctions tendances, Université catholique de Louvain, Centre universitaire de Médecine générale et Socio-Economie de la Santé, 1990, 43 pp.
7) Code de déontologie médicale, art. 33 et 42, Loi du 6.1.1978, art. 40.
8) A savoir : dans le cadre de l'exercice du droit d'enquête conféré aux Chambres par l'article 40 de la Constitution, dans le cadre de l'instruction d'une affaire par le Comité de surveillance de la Banque-carrefour ou lorsque la loi le prévoit ou l'oblige à faire connaître ce qu'il fait, Loi du 15.1.1990 relative à l'institution et à l'organisation d'une Banque-carrefour de la sécurité sociale, (M.B. 22.2.1990, p. 3 288 ss), art. 28.
9) Arrêté Royal du 18.3.1988 instituant un Conseil supérieur pour la coordination de la lutte contre le Sida (M.B. du 2.4.1988).
10) Arrêté Royal n° 78, du 10.11.1967 relatif à l'exercice de l'art de guérir, de l'art infirmier, des professions paramédicales et aux commissions médicales (M.B. du 14.11.1967, art. 13, errata au M.B. du 12.6.1968).
11) Code de déontologie médicale, article 39.
12) Circulaire du 31.3.1988 du Ministère de la Santé publique et de l'Environnement, Administration des Etablissements de soins, adressée aux Directions des hôpitaux et aux médecins-chefs.
13) Le médecin peut confier à des praticiens de l'art infirmier et des professions paramédicales, l'exécution de certains actes préparatoires au diagnostic ou relatifs à l'application du traitement ou à l'exécution de mesures de médecine préventive, Arrêté Royal n° 78 du 10.11.1967, relatif à l'exercice de l'art de guérir.
14) Arrêté Royal n° 78 du 10.11.1967, art. 14 et Code de déontologie médicale, art. 109.

15) Annexe à l'Arrêté Royal du 16.11.1973 établissant la nomenclature des prestations de santé en matière d'assurance obligatoire contre les maladies et l'invalidité.
16) L'article 119 du Code de déontologie médicale est plus nuancé encore : le médecin chargé d'expertiser la capacité ou la qualification physique ou mentale d'une personne, ou de procéder à toute exploration corporelle, de contrôler un diagnostic ou de surveiller un traitement ou d'enquêter sur les prestations médicales pour compte d'un organisme assureur (art. 119) ne peut consulter un dossier médical sans l'accord du patient et sans l'autorisation du médecin responsable du traitement, auxquels il aura fait connaître sa qualité et sa mission (art 130). Il appartient au médecin traitant ou au médecin chef de service hospitalier, ayant la responsabilité du dossier du malade, de décider quels documents il peut communiquer (art. 130).
17) Loi du 9 août 1963, instituant et organisant un régime d'assurance obligatoire contre la maladie et l'invalidité, article 84 modifié (loi du 24.12.1963, du 8.4.1965) et Arrêté Royal du 22/23.3.1982 et Arrêté Royal n° 533 du 31.3.1987, textes coordonnés par l'Institut national d'Assurance maladie-invalidité.
18) Principalement,
- Loi du 9.8.1963 instituant et organisant un régime d'assurance obligatoire contre la maladie et l'invalidité et ses très nombreux arrêtés d'exécution et :
- Loi sur les hôpitaux, coordonnée le 7.8.1987, et ses très nombreux arrêtés d'exécution.
19) Arrêté loi du 24.1.1945 relatif à la prophylaxie des maladies vénériennes (M.B. 26.1.1945).
20) Arrêté Royal du 1.3.1971 relatif à la prophylaxie des maladies transmissibles (M.B. 23.4.1971)
21) Cf. note 9).
22) Arrêté Royal du 20.12.1973 portant fixation des règles suivant lesquelles le pouvoir organisateur de l'hôpital communique au Ministre qui a la santé publique dans ses attributions notamment les renseignements statistiques se rapportant à son établissement (M.B. 29.1.1974, art. 3, paragraphe 2).
23) Code civil, art. 55, 56, 57, modifiés par la loi du 30 mars 1984 et circulaire du Ministère de l'Intérieur du 19 décembre 1978.
24) Art. 8.
25) Code pénal, art. 458.
26) R. GROSEMANS, op. cit., pp. 335-336.
27) R. GROSEMANS, Le secret professionnel et l'hôpital, Bulletin d'information de l'INAMI, 1979, p. 333.
28) Code de déontologie médicale, art. 57.
29) RYCKMANS, R., et MEERT-VAN DE PUT, R., Les droits et les obligations des médecins, Bruxelles, Larcier, Tome I, 1971, n° 172 (487 pp).
30) Code de déontologie médicale, art. 70.

31) A propos du secret, voir P. LAMBERT, Le secret professionnel, Bruxelles, Ed. Numesis, 3, avenue du Manoir, 1180 Bruxelles, 1985, 322 pp.
32) R. GROSEMANS, op. cit., p. 337.
33) Art. 17, Loi du 3.7.1978 relative aux contrats de travail.
34) Code de déontologie médicale, art. 55, exceptions, art. 58.
35) Loi du 8.4.1965 instituant les règlements de travail, art. 6, sixièmement.
36) Ibid, art. 16.
37) Voir art. 13 de la loi sur les hôpitaux, coordonnée le 7.8.1987 (M.B. 7.10.1987), p. 14652 et SQ., titre 4. (dispositions spécifiques relatives à la gestion des hôpitaux et au statut des médecins hospitaliers).
38) Circulaire du Ministère de la Santé Publique aux directions des hôpitaux et aux Médecins-chefs, 31.3.1988.
39) Question n 83, de Monsieur Lenfant, du 10.4.1984, Bul. Questions et Réponses, n 7.
40) Loi du 15.1.1990, op. cit., art. 28.
41) Projet de loi relatif à la protection de la vie privée à l'égard des traitements automatisés de données à caractère personnel.
42) Par exemple la Convention du Conseil de l'Europe, art. 5a. (à condition que les moyens de collecte soient licites et loyaux).
43) - Conseil de l'Europe :
. Convention n 108 pour la protection des personnes à l'égard du traitement automatisé des données à caractère personnel et
. Recommandation n R (86)1 du 23.1.1986 du Comité des Ministres du Conseil de l'Europe relative à la protection des données à caractère personnel utilisées à des fins de sécurité sociale (Comité des Ministres, 23.1.1986, 392ème reunion des délégués)
. Recommandation n R (89) du 6.3.19898 relative à la collecte d'informations épidémiologiques.
. Recommandation n R (89) 14 du 24.10.1989 sur les incidences éthiques de l'infection VIH dans le cadre sanitaire et social et
- O.C.D.E. : Directive concernant la protection de la vie privée et les flux transfrontaliers des données à caractère personnel.
44) Recommandation du Comité des Ministres du Conseil de l'Europe du 23.1.1986 relative à la réglementation applicable aux banques de données médicales informatisées.
45) Cf. analyse in : Y. POULLET et M.H. BOULANGER, La carte santé à mémoire, aspects juridiques.
46) Loi du 15.1.1990 relative à l'institution et à l'organisation d'une Banque-Carrefour de la sécurité sociale, (M.B. du 22.02.1990, pp. 3288), art. 28.
47) PIETERS, D., La Banque-carrefour de la sécurité sociale et la protection de la vie privée, Revue belge de Sécurité sociale, n spécial, 1989, p. 54.
48) Loi du 8.8.1983 organisant le Registre national des personnes physiques (M.B. 21.4.1984).

49) Avis du Conseil National de l'Ordre, 15.4.1989, Bulletin du Conseil de l'Ordre, 1989, n 45, p. 22.
50) Conseil National, 16.5.1987, Bulletin du Conseil National de l'Ordre des Médecins, 1987, n 37, p. 28.
51) Loi du 15.1.1990, op. cit., art. 26.
52) PIETERS, D., La Banque-carrefour de la sécurité sociale et la protection de la vie privée, Revue belge de sécurité sociale, n spécial, 1989, p. 61.
53) Loi du 15.1.1990, op. cit., art. 26.
54) Ibid., art. 26.
55) Loi du 15.1.1990, op. cit., art. 14.
56) Décret de la Communauté flamande du 23.12.1986, portant instauration de la carte uniforme d'urgence médicale (M.B. 1.3.1987), art. 3.
57) Réponse du Conseil National de l'Ordre des Médecins, 7 septembre 1988 au Ministère de la Communauté Française.
58) Conseil National de l'Ordre des Médecins, Bulletin du Conseil, 1987, n 37, p. 28.
59) Ibid, p. 29.
60) Loi du 15.1.1990, op. cit., art. 15.
61) Ibid, art. 46.
62) PIETERS, D., op. cit., p. 57.
63) Loi du 15.1.1990, op. cit., art. 61.
64) PIETERS, D., op. cit., pp. 59 et 63.
65) Le Comité des Ministres du Conseil de l'Europe avait d'ailleurs été prudent, en recommandant que les décisions concernant les flux de données se fassent en pesant les intérêts de toutes les parties concernées.
66) Conseil de l'Europe, Convention du 28.1.1981, op. cit., art. 5a.
67) Projet de loi relatif à la protection de la vie privee à l'égard des traitements automatisés de données à caractere personnel.
68) Décret de la Communauté flamande du 23.12.1986, op. cit., art. 3.
69) Seance du 21.11.1987 concernant l'arrêté d'application de l'Exécutif flamand du 25.6.1987.
70) Réponse du 7.9.1988 au Ministère de la Communauté française.
71) Convention n 108 du Conseil de l'Europe, art. 6; Recommandation du Comité des Ministres du Conseil de l'Europe, paragraphes 3.1 et 3.3; Directive de l'O.C.D.E., paragraphe 7.
72) Conseil de l'Europe, Annexe à la Recommandation n R (86) 1 du Comité des Ministres des Etats membres, op. cit., art. 3.1. et la Convention n 108, ajout concernant la santé et la vie sexuelle
73) Conseil de l'Europe, Convention n 108 pour la protection des personnes à l'égard des traitements automatisés des données à caractère personnel, Strasbourg, 28.1.1981, article 6.
74) Bulletin du Conseil de l'Ordre, 1989, n 43, p. 37.
75) Conseil de l'Europe, Convention n 108, op. cit., art. 8; Directive O.C.D.E., op. cit., paragraphe 13.

76) Conseil de l'Europe, Recommandation R (86) 1, op. cit., art. 6.1.
77) Convention du Conseil de l'Europe, op. cit., art. 5d.
78) Loi du 15.1.1990, op. cit., art. 20.
79) Loi du 15.1.1990, op. cit., art. 20.
80) Ibid, op. cit., art. 20, paragraphe 3.
81) Conseil de l'Europe, Recommandation R (86) 1, op. cit., art. 9.1, et Conseil de l'Europe, Convention n 108, op. cit., art. 5.1.
82) Ibid., art. 9.3.
83) PIETERS, D., op. cit., pp. 50 et 53.
84) Projet de loi relatif à la protection de la vie privée à l'égard des traitements automatisés de données à caractère personnel.
85) Avis du Conseil National de l'Ordre des Médecins, Bulletin du Conseil National de l'Ordre des Médecins, 1989, n 45, p. 22.
86) Ibid et Art.109 du Code de déontologie médicale.
87) Arrêté Royal du 1.3.1971 relatif à la prophylaxie des maladies transmissibles (M.B. 23.4.1971).
88) Arrêté ministériel d'exécution du 18.3.1974 de l'Arrêté Royal du 13.3.1974 relatif à l'agréation des services de dépistage des anomalies congénitales métaboliques et à l'octroi de subventions à ces services (M.B. du 8.8.1974) et Arrêté Royal du 7.11.1973 portant création du Conseil supérieur de la génétique humaine.
89) Art. 79 du Code civil.
90) Circulaire du Ministère de l'Intérieur du 19.12.1978.
91) Arrêté Royal du 12.8.1987 déterminant les règles suivant lesquelles certaines données statistiques doivent être communiquées au Ministre qui a la santé publique dans ses attributions (M.B. 25.8.1987).
92) Circulaire du 5.2.1988 du Ministère de la Santé publique, Administration des établissements de soins, comptabilité et gestion des hôpitaux, aux organes de gestion des hôpitaux concernant la communication d'une série minimale de données infirmières, administratives et médicales.
93) Conseil National, 16.5.1987, Bulletin du Conseil de l'Ordre des Médecins, 1987, n 37, pp. 27-28.
94) Circulaire du 5.2.1988 du Ministère de la Santé Publique, (Administration des établissements de soins, comptabilité et gestion des hôpitaux) aux organes de gestion des hôpitaux, conformément à l'art. 86 de la loi coordonnée sur les hôpitaux et à l'Arrêté Royal du 14.8.1987.
95) Arrêté royal du 4.8.1986 (M.B. 21.8.1986).
96) Loi du 15.1.1990, op. cit., art. 5.
97) Code de déontologie médicale, art. 43.
98) Ibid, art. 62.
99) Loi du 4.7.1962 relative à la statistique publique (M.B. 20.7.1962).
100) Bulletin du Conseil de l'Ordre des Médecins 1989, n 45, p. 22 (A propos de la médecine du travail).
101) Avis du Conseil National du 16.5.1987, Bulletin du Conseil de l'Ordre des Médecins, 1987, n 37, p. 28.

102) Bulletin du Conseil de l'Ordre des Médecins, 1987, n 37, p. 16.
103) Normalisation des informations médicales pour les soins ambulatoires dans la Communauté européenne, CEE, Programme AIM, Projet CHIC, 1989, 29 pp.
104) Recommendation n R (89)4 of the Committee of Ministers to Member-States (6 March 1989) on the collection of epidemiological data on primary health care.
105) THIRION, X., SAMBUC, R. et SAMMARCO, J.L., L'anonymat dans les enquêtes épidemiologiques : étude et mise en oeuvre d'une nouvelle méthode, Paris, Revue d'épidemiologie et de santé publique, 1988, volume 36, pp. 36-42.